October 19, 1999

Docket No. 99D-2335
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

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Dear FDA Representative,

I am submitting comments on:
- FDA Medical Glove Guidance Manual Draft. released on July 30, 1999, and
- 21 CFR Parts 801, 878, and 880, Surgeon's and Patient Examination Gloves; Reclassification and Medical Glove Guidance Manual Availability; Proposed Rule and Notice, dated July 30, 1999

The following recommendations are made:
1) FDA standards for medical gloves must require that gloves demonstrate resistance to penetration of blood borne pathogens (BBPs), as judged by passing ASTM F1671 during the entire shelf life of the gloves.
2) FDA must incorporate standards for testing gloves in a way that models typical workplace conditions. In the workplace, gloves may be simultaneously subjected to physical stressors (e.g. stretching, flexing), perspiration, and chemicals or chemotherapy drugs. It is essential that gloves provide an impenetrable barrier to blood borne pathogens under these conditions.

Because medical gloves are used to protect against blood borne pathogens (BBPs), it is essential that gloves are tested to ensure that BBP protection is provided. Currently, the FDA does not require a manufacturer to test a glove's resistance to penetration by a BBP. This is unacceptable. A current FDA testing procedure which evaluates leakage of a water-filled glove within 2 minutes is inadequate for predicting BBP barrier capability. ASTM F1671, which evaluates BBP penetration, is a reasonable test and the FDA should require that medical gloves pass this test throughout their shelf life.

In addition, current FDA glove requirements fail to consider that in a medical setting, gloves encounter a combination of stressors simultaneously. Frequent glove failures, including tears and leaks (which are often unrecognized until a glove is removed) attest to the fact that current standards are inadequate for protecting workers. The FDA is urged to incorporate medical glove criteria which better typify the conditions under which gloves are employed to protect workers against blood borne pathogens.

Sincerely Yours,

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99D-2335

C2

HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CROSS REFERENCE SHEET

Docket Number/Item Code: 99D-2335/C2

See Docket Number/Item Code: 98N-0313/C21

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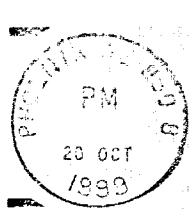

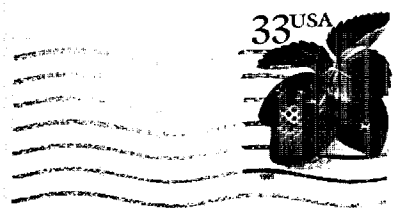

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